Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 41-61 are pending in the application, with claims 41, 42, 43, and 54 being the independent claims. Claims 15-40 are sought to be canceled without prejudice to or disclaimer of the subject matter therein. Claims 1-14 were previously canceled. New claims 41-61 are sought to be added. Support for the new claims can be found throughout the specification, *inter alia,* in Examples 1, 2, and 15, Table 1, and in the claims as originally filed. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 15, 22-26, 29-31, 33, and 36 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner asserts that the specification does not provide enablement for a composition comprising peptides that are less than 15 amino acids in length and comprise the epitopes of SEQ ID NOs: 2, 3, or 4, or methods for treating breast cancer using the composition. Not in acquiescence to the propriety of the rejection, but rather solely to advance prosecution, claims 15, 22-26, 29-31, 33, and 36 have been canceled.

Therefore, the rejection has been rendered moot. Applicants respectfully traverse the rejection as it may be applied to the claims presented herein.

In order for a claim to be enabled, the specification must teach one of ordinary skill in the art to make and use the invention without undue experimentation. The factors that can be considered in determining whether an amount of experimentation is undue have been set forth in *In re Wands*, 858 F.2d731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Among these factors are: 1) the guidance provided by the specification; 2) the amount of pertinent literature; 3) the presence of working examples; and 4) the predictability of the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. *See Id.*

The Examiner provides the conclusory statement, "one cannot predict that a peptide of less than 15 amino acids and comprises a CTL epitope of SEQ ID NO:2, SEQ ID NO:3, or SEQ ID NO:4 could still induce a CTL response, because one cannot predict the effect of surrounding amino acids on the function of the CTL epitope of SEQ ID NO:2, SEQ ID NO:3, or SEQ ID NO:4." in support of her assertion. The Examiner then relies on the disclosure from several references including Bergmann *et al.* and Eisenlohr *et al.* to support the assertion that surrounding amino acids have an "unpredictable" effect on the function of a CTL epitope; and therefore the claimed compositions are not enabled, nor is their use to treat cancer.

The Examiner focuses on "predictability" of the peptide's characteristics for reasons of non-enablement. However, Applicants note that although the predictability of the art can be considered in determining whether an amount of experimentation is undue,

mere unpredictability of the result of the experiment is not a consideration. Indeed, in *In re Angstadt*, the court specifically cautioned that the unpredictability of the result of an experiment is not a basis to conclude that the amount of experimentation is undue. 537 F.2d 498, 503 (CCPA 1976). The court disagreed with the proposition that, to be enabling, a disclosure must provide guidance such that one of ordinary skill in the art has a "reasonable certainty" of the outcome before performing an experiment. *Id.* The court stated:

> [if this proposition were true,] then all "experimentation" is "undue," since the term "experimentation" implies that the success of the particular activity is uncertain. Such a proposition is contrary to the basic policy of the Patent Act.

Id. As explained in *In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991), the statutory enablement requirement is satisfied if the specification "adequately guides the worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility."

Applicants respectfully assert that the experimentation required to make and test all of the peptides encompassed by the claimed invention is routine. The present specification provides data on MHC binding and CTL recognition/activation for the peptides of SEQ ID NOs:2-10. Furthermore, the specification provides ample description of assays to make and test peptides that are encompassed by the claimed invention. For example, teaching related to binding affinity can be found, *inter alia*, at paragraphs 169-174, and assays to detect T cell responses can be found, *inter alia*, at paragraphs 200-206. Therefore, using nothing more than the teachings of the

specification and the general knowledge in the art, one of ordinary skill could make, test, and use the claimed compositions to treat cancer without undue experimentation.

In addition, the claimed compositions are currently the subject matter of an Investigational New Drug (IND) application to treat cancer (*see,* specification at Example 15). The IND identification number for the claimed compositions is BB-IND 10802. The potential indications include lung cancer, colorectal cancer, and breast cancer. A Phase 1 study was conducted in lung cancer and colorectal cancer patients, and a Phase 2 study was conducted in lung cancer patients. The IND study is still open. Applicants respectfully point out that MPEP 2107.03 IV states, "[T]hus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility." Accordingly, Applicants respectfully traverse the rejection as it may be applied to the claims presented herein.

Rejections under 35 U.S.C. § 102

Claims 15, 22-26, and 29-30 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Fikes *et al.* (U.S. Pat. No. 6,602,510). Not in acquiescence to the propriety of the rejection, but rather solely to advance prosecution, claims 15, 22-26, and 29-30 have been canceled. Therefore, the rejection has been rendered moot. Applicants respectfully traverse the rejection as it may be applied to claims presented herein.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); *see also* MPEP

§ 2131. New claims 41-54 each require a composition comprising at least the peptides RLLQETELV (SEQ ID NO:2), YLQLVFGIEV (SEQ ID NO:3), LLTFWNPPV (SEQ ID NO:4), SMPPPGTRV (SEQ ID NO:5), KLBPVQLWV (SEQ ID NO:6), KVFGSLAFV (SEQ ID NO:7), and YLSGADLNL (SEQ ID NO:8). Fikes *et al.* does not disclose the peptide YLSGADLNL (SEQ ID NO:8). Therefore, Fikes *et al.* does not disclose each and every element of the claims presented herein. Accordingly, Applicants respectfully request that the rejection be reconsidered as it may be applied to the claims presented herein.

Rejections under 35 U.S.C. § 103

Claim 31 was rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Fikes *et al.* (U.S. Pat. No. 6,602,510), in view of Reed *et al.* (U.S. Pat. No. 6,432,707). Not in acquiescence to the propriety of the rejection, but rather solely to advance prosecution, claim 31 has been canceled. Therefore, the rejection has been rendered moot. Applicants respectfully traverse the rejection as it may be applied to claims presented herein.

In order to establish a *prima facie* case of obviousness, the proper analysis is to first consider whether the following three criteria are met: (1) there must be some reason, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2143. "[I]n formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary

skill in the art would have combined the prior art elements in the manner claimed." Memorandum from the United Patent and Trademark Office, "Supreme Court decision on *KSR Int'l. Co. v. Teleflex Inc.*," (May 3, 2007) at page 2. Applicants respectfully assert that the combination of the references do not teach or suggest all of the claim limitations, and thus the third criteria necessary to establish a *prima facie* case of obviousness has not been met.

As stated above, new claims 41-54 each require a composition comprising at least the peptides RLLQETELV (SEQ ID NO:2), YLQLVFGIEV (SEQ ID NO:3), LLTFWNPPV (SEQ ID NO:4), SMPPPGTRV (SEQ ID NO:5), KLBPVQLWV (SEQ ID NO:6), KVFGSLAFV (SEQ ID NO:7), and YLSGADLNL (SEQ ID NO:8). Fikes *et al.* does not disclose the peptide YLSGADLNL (SEQ ID NO:8). The deficiencies of Fikes are not cured by Reed. Reed generally discloses the use of adjuvants, but does not disclose the peptides of the invention. Therefore, Fikes *et al.* and Reed *et al.* do not teach or suggest each element of the claims. Accordingly, Applicants respectfully request that the rejection be reconsidered as it may be applied to the claims presented herein.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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